## REMARKS

Claims 39-53 and 59-63 are currently pending in the present application. Claims 1-38 and 54-58 have been canceled without prejudice or disclaimer thereto. Accordingly, claims 39-53 and 59-63 are currently under consideration.

Claims 39, 42, 43, 47 and 49 have been amended. Claims 39 and 49 have been amended to recite at least one excipient is used with ribavirin to form a mixture. Claim 39 has been further amended to recite the step of forming a uniform mixture into a granulated mass and shaping the granulated mass into the ribavirin particles. Claims 42 and 43 have been amended to be consistent with independent claim 39. Claim 47 was amended to recite mixing ribavirin, microcrystalline cellulose and povidone. Adequate written descriptive support for these amendments can be found throughout the original application including the original claims. Accordingly, no new matter issues are raised by these amendments.

Claims 59-63 are new. Support for the new claims can be found throughout the application including the original claims. Accordingly, the addition of these new claims raise no new matter issues.

**35 U.S.C. §112, 1st**

Claims 39-58 were rejected under 35 U.S.C. §112, first paragraph, as allegedly lacking written descriptive support. The rejection is traversed and reconsideration is respectfully solicited.

Claims 54-58 have been cancelled without prejudice and, accordingly, the rejection of these claims is now moot. Claims 39-53 and 59-63 are in full compliance with 35 USC 112.

In the Office Action, the Examiner asserted that in this application the particular number and particular identities of the excipients and the particular conditions of their processing in the presence

of ribavirin, represent the essence of the invention being claimed but have only been claimed generically and have not bee claimed in detail. The Examiner further asserts that a review of the instant claims and the instant disclosure suggest that presently Applicant may not have made a complete disclosure and therefore may be attempting to patent a process portions of which have neither been disclosed nor claimed. The Examiner recommends that Applicant supplement the instant disclosure to fill in details or to take other appropriate actions.[1] Applicant respectfully traverses these assertions.

Initially, it should be noted that the "essence of the invention" resides in the claimed subject matter. Secondly, Applicant has not made a limiting disclosure; nor can the Examiner identify anywhere in the disclosure where Applicant has limited its invention to any particular number or identity of excipient, or condition because there is no such limitation in the disclosure. Moreover, it is unclear what basis the Examiner is relying upon to conclude that the disclosure is "incomplete". No explanation is given. Accordingly, Applicant respectfully requests clarification of these assertions.

The germane issue for written descriptive support is whether one of skill in the art would have recognized Applicant had possession of the claimed subject matter. The claims at issue recite processes of forming ribavirin mixtures and particles. The specification fully supports the claimed subject matter. In particular, Applicant respectfully directs the Examiner's attention to the original claims which are part of the original application. *Union Oil Co. v. Atlantic Richfield Co.*, 208 F.3d at 998 n.4, 54 USPQ2d at 1233 n.4 (Fed. Cir. 2000)("One of this court's predecessor courts clarified that disclosure in an originally filed claim satisfies the written description

[1] In rejecting claims 39-58 for allegedly lacking written descriptive support, the Examiner cites to *Brenner v. Manson*, 148 USPQ 689, 696 (US 1966). However, the statutory provision at issue in Brenner was utility, not written description. In Brenner, the Applicant failed to disclose any legally cognizable utility for his invention. In the present application, utility is unquestionably established. Hence, Brenner is inapplicable.

requirement."). As described in original claim 1, Applicant claimed subject matter directed to mixing ribavirin with at least one excipient to form a mixture. Clearly, Applicant has written descriptive support for processes of forming ribavirin mixtures that include mixing ribavirin with at least one excipient.

Accordingly, it is respectfully submitted that claims 39-53 and 59-62 are fully supported by the originally filed application and that those of ordinary skill in the art would have recognized that the inventor had possession of the claimed subject matter at the time of the filing of the original application. Reconsideration and withdrawal of the rejection are respectfully solicited.

**35 U.S.C. §112, 1st**

Claims 39-58 were rejected under 35 U.S.C. §112, first paragraph, as allegedly lacking enablement. The rejection is traversed and reconsideration is respectfully solicited.

Claims 54-58 have been canceled without prejudice and, accordingly, the rejection of these claims is now moot. Claims 39-53 and 59-63 are in full compliance with 35 USC 112.

In the Office Action, it was asserted that the scope of the claims were excessive in light of the specific embodiments provided in the present application and that the claims failed to define the number of, or the particular identities of, the excipients in the claims which allegedly rendered them non-enabled. Applicant respectfully traverses these assertions.

The test for enablement is whether one of ordinary skill in the art can make and use the claimed subject matter without undue experimentation. See, e.g., *In re Wands*, 8 USPQ 2d 1400, 1404 (Fed. Cir. 1988), MPEP 2164.01. There are many factors to be considered when determining enablement. These include, without limitation, claim breadth, the nature of the invention, the state of the prior art, the level of ordinary skill in the art, the level of predictability in the art, the amount

of direction provided by the disclosure, the existence of working examples, and the quantity of experimentation needed to make or use the claimed subject matter on the content of the disclosure. See MPEP 2164.01. The Examiner has not made a single finding or provided any basis cognizable under any of these factors for determining whether the instant disclosure enables the claimed subject matter. Applicant respectfully submits that the Examiner's bald conclusorary remarks are insufficient to sustain an enablement rejection.

Rather, the evidence of record establishes that the claims fully satisfy the enablement requirement of 35 USC 112. The nature of this invention relates to the pharmaceutical formulation arts and the level of skill in that art is provided by at least the references cited by the Examiner. Those references show that those of skill in the art are knowledgeable about formulating pharmaceutically active ingredients with excipients. These references further show that the pharmaceutical arts is a relatively mature art and that the level of predictability for selecting a particular excipient with a pharmaceutically active compound does not involve undue experimentation. Moreover, Applicant provided several working examples in its specification. Given the direction provided in the instant disclosure and the state of the art to which the application pertains, the claims do not require undue experimentation to practice. Accordingly, it is respectfully submitted that one of ordinary skill in this art would undertake little, if any, experimentation to make a ribavirin particle or ribavirin mixture as claimed based on the application disclosure and state of the art. Reconsideration and withdrawal of the rejection are respectfully solicited.

**35 U.S.C. §112, 2d**

Claims 39, 43, 47, 51 and 54-56 were rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite. The rejection is traversed and reconsideration is respectfully solicited.

Claims 54-56 have been cancelled without prejudice and accordingly, the rejection of these claims is now moot. Claims 39, 43, 47, 51 and 59-63 fully comply with 35 USC 112.

In the Office Action, it was asserted that the use of the terms "excipient" and "binder" render certain claims indefinite because the identity or the identities of the excipient and binder have not been provided in the remainder of the claim. Applicant respectfully traverses these assertions.

The threshold issue under 35 USC 112, second paragraph, is whether a person of ordinary skill in the art would have understood the metes and bounds of the claimed subject matter and not whether other suitable language should be used. See MPEP 2173.02. The term "excpient" and "binder" is unquestionably understood by those skilled in the art to which the application pertains. In fact, the references applied by the Examiner in the Office Action used these very terms. Hence, this is evidence that those of skill in the art understand the terms excipient and binder. Nothing more is required for definiteness under the law. Accordingly, reconsideration and withdrawal of the rejection are respectfully solicited.

**Double-Patenting**

Claims 39-54 were rejected under the doctrine of obviousness-type double patenting over claims 1-17 of U.S. No. 6,720,000. The rejection is traversed. Nonetheless, Applicant respectfully requests that the rejection be held at abeyance until allowable subject matter is identified.

**35 U.S.C. §103**

Claims 39-54 were rejected under 35 U.S.C. §103(a) as being unpatentable over Tam '097 in view of Liebowitz and further in view of Rudnic and Porter. The rejections are traversed and reconsideration is respectfully solicited.

Independent claims 39 and 59 are directed to a process of forming ribavirin particles; while independent claims 47, 49 and 51 relate to processes of forming ribavirin mixtures. The dependent claims further define the processes of the independent claims. In each of these claims, water is added or combined with ribavirin. None of the cited references suggest this step - - in fact, certain references teach away from this.

As noted by the Examiner, Tam does not disclose, teach or suggest any process steps for the preparation of any pharmaceutical composition. Tam simply discloses that ribavirin compositions were known prior to Applicant's application.

Liebowitz, a secondary reference, teaches a process using "dry" compaction. (See, e.g., column 1, lines 30-34; column 1, line 52; column 4, beginning at line 65, the section titled "Manufacturing Procedure".) Liebowitz recognizes many processing difficulties in preparing ribavirin compositions, including flowability, uniformity, etc. (See, e.g., column 1, lines 15-29). However, to solve these processing difficulties, Liebowitz teaches a process that explicitly excludes a wetting agent.

In many respects, the Liebowitz process is the opposite of the claimed process. There is no teaching or suggestion anywhere in Liebowitz relating to the use of a wetting agent, as recited by claim 54, let alone adding water to a ribavirin mixture, as recited by claims 39-53 and 57-58.

Moreover, there is no teaching or suggestion in Liebowitz of a drying step, as recited by claims 47-54. The lack of this step is not surprising since Liebowitz never suggests wetting its mixture in the first instance.

Hence, the combination of Tam and Liebowitz would not motivate one skilled in the art at the time to arrive at the presently claimed subject matter. Tam has nothing to do with the preparation of ribavirin compositions and Liebowitz teaches preparation steps that are the

opposite of the present process claims. Accordingly, it is respectfully submitted that the combination of Tam and Liebowitz not only fails to reach the presently claimed process but, in fact, teaches away from it.

The additional secondary references do not cure the deficiencies of Tam and Liebowitz. Rudnic relates to general production methods for preparing oral solid dosage forms and Porter teaches general techniques for applying coatings to solid dosage forms.

The secondary references teach dry and wet processes. They teach ingredients for fast dissolving and sustained release formulations. They teach nothing specifically regarding the preparation of a ribavirin composition and there is no reason why one of ordinary skill in the art at the time would pick and choose among the general teaching of these secondary references to arrive at the presently claimed subject matter.

Indeed, Liebowitz has already taught a process that allegedly solves many of the art recognized difficulties of preparing ribavirin solid dosage forms. Hence, those skilled in the art would be motivated to follow the dry compacting process of Liebowitz. Given the problems associated with ribavirin formulations, as identified by Liebowitz, it is respectfully submitted that one of skill in the art would not expect success in practicing the opposite of what Liebowitz teaches.

Hence, it is respectfully submitted that the combination of cited art, and art known as of the filing date of the present application, would not have lead one of skill in the art to a process of preparing a ribavirin composition, with a likelihood of success, by adding a wetting agent or water thereto, as recited in claims 39-53 and 59-63.

Based on the forgoing, it is respectfully submitted that the claims in the application are patentable. Accordingly, reconsideration and allowance of the application are respectfully solicited.

To the extent necessary, a petition for an extension of time under 37 C.F.R. 1.136 is hereby made. Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 500417 and please credit any excess fees to such deposit account.

Respectfully submitted,

McDERMOTT WILL & EMERY LLP

Daniel Bucca, Ph.D.
Registration No. 42,368

600 13th Street, N.W.
Washington, DC 20005-3096
Phone: 202.756.8000 DB:ajb
Facsimile: 202.756.8087
**Date: October 31, 2007**

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